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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,348	07/29/2003	Navin Vaya	1296-016	9293

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HEDMAN & COSTIGAN P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
11/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,348	VAYA ET AL.	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8-30-07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants Amended Claims, Remarks and Amendments to the specification filed on August 28, 2007 is acknowledged. Claims 1-60 remain pending in this application. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claims 21-24 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim, in this instance, claim 10. See MPEP § 608.01(n). Accordingly, the claims 21-28 not been further treated on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-11, 14-27, 29-33, 36-41, 44-46, and 48-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santus et al. (US Patent 5,472,704).

Santus discloses a pharmaceutical composition for the controlled release of medicinal drugs, which has the property of adhering to biologic tissues. The characteristic features of the composition are a plurality of small-size units capable of ensuring a gradual release of the active ingredient they contain the units being coated with a bioadhesive polymer layer. The composition makes it possible to keep the release controlling function separate from the function providing bioadhesion and can

be adapted inter alia to oral, ocular, rectal, vaginal, nasal or periodontal administrations (abstract).

The composition includes: a) a multiplicity of microunits containing an active ingredient and at least one component which controls the release of the active ingredient in the environment of the use point for said composition, said component not substantially contributing to bioadhesive properties of said composition; b) a coating for these microunits, comprising at least one bioadhesive material said coating being capable of ensuring adhesion of the microunits to the tissues or membranes of said use point; and, optionally; c) an excipient which, depending on the route of administration selected, promotes delivery of the composition at the use point and/or permits retention of the pharmaceuticals effectiveness of the composition during administration and at the use point (column 3, lines 41-59). Santos further discloses the microunits can include matrix units (column 4, line 40). The release of a very soluble active ingredient can be slowed down to the desired rate by using a hydrophobic matrix as the release-controlling component. . Acceptable sizes of units are from 1-2000 microns (column 5, lines 29-43).

Acceptable polymers for use include polyacrylic polymers; cellulose derivatives such as hydroxypropylmethycellulose, hydroxyethylecellulose, hydroxypropylcellulose and sodium carboxymethylcellulose; natural polymers such as gelatin, sodium alginate and pectin (column 6, lines 4-40). For administration by oral route, the microunits are carried within a capsule or tablet. The microunits are inclined to adhere to one another and may therefore be additionally coated with a hydrophobic agents, including stearic

acid, magnesium stearate, calcium stearate, zinc stearate, talc, glyceryl fumerate, hydrogenated vegetable oils, and polyethylene glycols (column 7, lines 30-35).

The active agent can be selected from analgesics, antibacterials, antibiotics, anticonvulsants, antidepressants, antidiabetics, antifungals, antihistaminics, antihypertensives, anti-inflammatories, antiparkinsonian drugs, antipyretics, anticholinergic drugs, antimicrobials, antiviral drugs, antiulceratives, bronchodilators, cardiovascular drugs, contraceptives, decongestants, diuretics, anti-hypoglycemics, hormones, ophthalmic drugs, hypnotics, sympathomimetic drugs, tranquilizers and vitamins (column 5, lines 51-61). Santos discloses additionally actives can be incorporated into the composition through routine experimentation and optimization.

Santos further discloses a method of making the tablets (see column 8, lines 7-60).

Santos does not disclose ratios of active agent to polymer. The instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the ratio of active agent to polymer, to prepare a composition with the desired release profile. A specific ratio having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues Santus does teach, in a very general manner, the use of hydrophobic release components for making controlled release formulations of highly soluble drugs. However, Santus fails to point the use of microunits for the controlled release of an active ingredient obtained singly from reservoir or matrix or osmotic or biodegradable units. Moreover, Santus disclose, that the preparation of controlled release microunits in use ofmatrix units is more complex than that of reservoir units (Column 4,"lines 60-61). Thus, Santus teaches away from a dual retard technique and discloses a preference for using the reservoir system. The examiner respectively disagrees with Applicants conclusion about Santus teaching away from the claimed invention. As noted in the body of the rejection above, Santos teaches the matrix of the instant claims with microns sized. The preference of a specific embodiment of Santus does not teach away from the other disclosed embodiments.

Claim 4-5, 12-13, 28, 34-35, 42-43, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santos et al. (US Patent 5,472,704) in view of Akiyama et al. (US Patent 5,399,357).

The teachings of Santos are disclosed above and applied in the same manner.

Santos does not disclose the use of Ammonio methacrylate copolymers or fatty acid esters.

Akiyama discloses a sustained release preparation comprising a matrix preparation comprising a pharmaceutically active agent dispersed in a matrix of a fatty acid ester of a polyglycerol, such as hydrogenated castor oil (column 4, lines 9-11). The matrix may be coated with an acrylic acid polymer such as Eudragit (column 6, lines 3-5).

It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of coating polymers and solubility regulators. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments regarding the Santus reference are discussed above and applied in the same manner. Applicant additionally argues in the amended claims, the micro matrix particles are further coated with rate controlling agents, whereas in Akiyama the coating of granules is done to reform their surfaces, mask their taste, or give them solubility in the intestine. Akiyama doesn't teach that coating of micro matrix granules can control the release. Hence the processes of preparing micro matrix particles as

recited in the amended claims are different than the process pointed out in Akiyama. Akiyama also fails to point out the coating of micro matrix particles in order to control release. Also note that Akiyama, as disclosed in all the examples (1-30), uses large amounts of fatty acid ester of polyglycerol (release controlling agent) to obtain desired release profile without having any burst release or dose dumping. Much like Santus, this will ultimately increase the size of the formulation. Contrary to both Akiyama and Santus, the amended claims recite dual retard techniques, which enable the size of the dosage form to be reduced considerably. It is noted that Applicants intended function of the coating may be different from the intended use of the prior art, however, absent a showing to the contrary, it is the examiners position that since the prior art teaches the same composition, which would possess the same functional limitations as the instant claims. Additionally, it is noted that Applicant is not claiming a specific final product size. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the size of the tablet) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Double Patenting

Claims 1-60 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-60 of copending Application No. 11/134631. This is a

provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-60 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-60 of copending Application No. 11/134632. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

No claim is allowable. Due to the new grounds of rejection, this action is made Non-Final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MSMercier

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600